Purged 5/19/1999 MW
HFI-35
M26028N

FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

May 17, 1999

WARNING LETTER

NWE-23-99W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bernard Paul Surette, Owner/President
Paul's Lobster Co.
339 Northern Avenue
Boston, Massachusetts 02110

Dear Mr. Surette:

On January 27, 28 and February 2, 1999, the Food and Drug Administration (FDA) conducted an inspection of your seafood processing plant, located at 339 Northern Avenue, Boston, Massachusetts. The Investigator documented serious violations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123), and the Good Manufacturing Practices (GMPs) requirements in 21 CFR 110. These violations cause your cooked ready-to-eat, fresh, vacuum packed lobster meat processed by your firm, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

- Your firm's critical limit of 140° F for cooking lobsters does not appear to be appropriate to inactivate all vegetative pathogens that may be present (123.6(c)(3). The Seafood HACCP Guide lists 180° F as the internal temperature that will assure inactivation of all vegetative pathogens of public health concern. Section 3.401.11 of the 1999 Food Code lists as a minimum temperature for fish and meat 145° F for 15 seconds. We are also aware of published minimum values, the equivalent of 158° F for 2 minutes to inactivate Listeria monocytogenes.

Your firm must therefore establish an appropriate critical limit, providing documentation that the cook time and temperature assures safety by inactivating vegetative pathogens and takes into account lobster size and batch size.

We recommend using time and temperature of cook on the critical limits for the cook step. Monitoring internal temperature of a number of lobsters may be appropriate if you have documented that the internal temperature achieved is consistently far in excess of that required by the process.

- If this product is vacuum packaged it must be frozen immediately after processing. Controls are not applied where critical control points should be located, 21 CFR 123.6(b). Proper controls need to be in place to assure the safety of the product from production to consumption. Processors of vacuum-packaged fish should expect that at some point during storage, distribution, display, or consumer handling, proper refrigeration (i.e. 38° F or less), required to inhibit the growth of C. botulinum type E will not be maintained. Even if the product is distributed "refrigerated," the temperature during such shipment may fluctuate and there is nothing in your Plan which would control the formation of toxin by C. botulinum during distribution.

  However, if the product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use ("Important, keep frozen until used, thaw under refrigeration"), then formation of C. botulinum toxin may not be a significant hazard during storage and distribution.

- The sanitation monitoring log does not cover all of the required sanitation elements.

The above identification of violations are not intended to be an all-inclusive list of deficiencies at your seafood processing plant. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, failure to correct the above deficiencies may affect your firm's ability to obtain European Union Certificates. As you know, FDA, as a service to the US seafood industry to facilitate the free flow of trade, has voluntarily undertaken to certify that seafood exports meet the EU's food safety requirements. Unless the above deficiencies are corrected, FDA may remove your firm from the EU list. In addition, until these deficiencies are corrected, the agency may not issue EU certificates for shipments.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their reoccurrence. Your response should include copies of any documentation demonstration that corrections have been made. If corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Bruce R. Ota, Compliance Officer, at the noted above. If your have any questions concerning this matter, please contact Mr. Ota at (781) 279-1675, x119.

Sincerely,

John R. Marzilli
District Director
New England District Office